SCIENTIFIC ABSTRACT

This is an open label, phase I clinical trial to evaluate the safety and immunological effects of administering IL-7-producing allogeneic and autologous melanoma cells to patients with metastatic melanoma. Three groups of 3 patients will receive 10^7 irradiated unmodified autologous tumor mixed with increasing numbers of an IL-7 transduced allogeneic melanoma cell line (M24). The numbers of M24 (IL-7) added will be adjusted to produce 10, 100 or 1,000 ng IL-7/24 hr *in vivo*. The vaccine will be given in 3 biweekly subcutaneous inoculations. The study design allows a careful dose-escalation evaluation of toxicity (local and systemic). A final group of 5 patients will receive 3 biweekly inoculations of their own melanoma cells transduced with an IL-7 retroviral vector.

The effect of these vaccine administrations on antitumor immunity will be measured by tumor cell skin tests, tumor biopsies, generation of specific antibody and generations of CTL precursors. Nonspecific immunological effects (NK, LAK, recall antigen skin tests) will also be serially monitored.